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## **Guidelines in disrepute: a case study of influenza vaccination of health care workers**

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## **Abstract**

### **Objective**

Practice guidelines are an important support tool for health behaviour change. However, the effective implementation of guidelines can be difficult and the gaps that exist between guidelines and practice may be intractable. In this paper we examine a neglected, but important, area: understanding the reasons why problems may develop in the implementation and uptake of practice guidelines. To do so we explore the existence of gaps in the translation of *evidence* into practice based guidelines for health promotion.

### **Approach**

Drawing on relevant literature we examine the case of influenza vaccination, in particular, guidelines that advise influenza vaccination for all health care workers. We highlight gaps between the actions advised within these guidelines and the relevant evidence and explore some of the processes that have amplified and obscured this evidence during the development of guidelines.

### **Implications**

The current processes that underlie the translation of evidence into practice guidelines risk the loss of the nuanced and rich information that is needed for individual decision-making. Where evidence is limited, the propagation of evidence-guidelines gaps, without transparency as to the basis of decision-making, compromises the credibility of guidelines and places at risk the many benefits that guidelines can provide.

### **Conclusion**

We argue that evidence-guideline gaps may arise because of a range of problems with the nature of the evidence used to justify the guidelines and the way in which that evidence is applied and interpreted. We suggest that these problems may bring potentially useful guidelines into disrepute.

## Introduction

Evidence-based practice guidelines are an important support tool for clinical practice, clinical decision-making and funding decisions at the policy level. Practice guidelines have the potential to offer improved efficiency and value for money with regard to service delivery, consistency in care and reduced morbidity and mortality.<sup>1</sup> Practice guidelines also support quality decision-making by health care workers (HCWs) and policy makers in an environment where research is constantly evolving. However, effective implementation of guidelines may be difficult, and many gaps between guidelines and practice remain resistant to intervention.<sup>2-4</sup> Considerable resources are invested in education, support measures, inducements and enforcement in order to encourage adherence to guidelines and reduce guidelines-practice gaps.<sup>2-4</sup>

In contrast, the gaps that exist between *evidence* and guidelines have been relatively neglected. We contend that such gaps *do* exist and that they have the potential to compromise the effectiveness of efforts in preventative health.

## Objective

In this paper, we explore the implications of gaps between evidence and guidelines through examination of a case study. The case study considers the gap between guidelines recommending influenza vaccination for all HCWs and the low uptake by HCWs in Australia and internationally. Focussing on this case study is useful in satisfying the objectives of this paper which are to highlight some of the less well recognised, and less frequently discussed, issues that underpin gaps in the translation of *evidence* into practice and to discuss the consequences thereof.

## What's the problem?

Despite the emphasis placed on the importance of high quality evidence to underpin policy and practice, the evidence used to support guidelines may be of inadequate quality or may be misused to underpin particular advocacy positions. We discuss here some of the ways in which the use or misuse of evidence in the development of guidelines can be problematic (summary provided in Table 1).

### Paucity of evidence

Questions about the nature of evidence and the relative value of different types of evidence are heavily debated in academia and the policy arena. Evidence based medicine arose from a scientific tradition which privileges the notion of 'facts' existing independent of the observer. Scientific methods reinforce this apparent separation through techniques such as randomisation and statistical analysis of outcome measures. Such approaches are invaluable in providing particular types of evidence to inform decision making but they are limited by the very characteristics which make them desirable, particularly for questions which must be researched in 'real world' conditions. In particular, evidence collection through randomised controlled trials may be unsuitable for public health interventions. Public health evidence is frequently collected through different frames of evidence such as cross-sectional studies or natural experiments (e.g. John Snow's pump handle or Richard Doll's work on cancer and smoking). Brownson et al suggest that strict adherence to a "hierarchy of study designs may reinforce an inverse evidence law by which interventions most likely to influence whole populations (e.g. policy change) are least valued".<sup>5, p.179</sup> In addition, none of the methods normally considered within the rubric of evidence production may be useful for translating evidence into practice.

### **Evidence extension**

Muir Gray notes that the “absence of excellent evidence does not make evidence-based decision making impossible; what is required is the best evidence available not the best evidence possible”.<sup>6, p.61</sup> However, in choosing public health interventions, the only evidence available may be studies carried out in controlled conditions with little relationship to real world circumstances.<sup>7</sup> There is also a temptation, in the absence of good evidence, to support ‘culturally’ shared beliefs and to extend evidence collected in related but different circumstances to support the intervention of choice. In extending the evidence, with application to the specific case, to a more general application, the applicability of the evidence may be uncertain. Extension of evidence might be considered to fall under the rubric of ‘expert opinion’. This might be acceptable if the uncertainties were recognised and acknowledged. However, as we discuss in our case study, they may be masked by citation bias and amplification to the point where they become the shared cultural belief of the specific expert community or ‘factoids’, assertions that are reported so often that they are considered to be true.<sup>8,9</sup>

### **Citation bias and amplification**

Citation practices may operate to obscure uncertainty that exists within research evidence. Steven Greenberg explores this issue,<sup>10</sup> particularly the way in which scientific claims become validated through citation patterns. For Greenberg, citation provides a public record of the belief system that is shared within a community. Therefore, analysis of citation patterns in relation to particular claims, provide insight into, not only what is written, but also *how* it is supported. Greenberg’s findings reveal how citation can be used as a tool of persuasion for particular claims. Greenberg suggests that the certainty of claims within medical research is constructed through citation in several ways, two of which he refers to as *citation bias* and *amplification*. He defines citation bias as ways that authors exclude primary data that weakens or contests the claims that they aim to represent as valid. In contrast, amplification occurs when a small number of papers, regardless of whether these are influential or peripheral, are cited repeatedly in support of particular claims without the concurrent presentation of new data. Both result in systematic support of particular claims and the loss of potentially valuable, but alternative, understandings.

### **Dead-end citation**

Dead-end citation is the use of citations as “tools of persuasion” to support a line of reasoning even though the citations do not contain relevant evidence.<sup>10</sup> It is not clear why authors would choose to cite papers which provide a dead-end for a reader. Gilbert suggests this may be to “provide justifications for the positions adopted in a paper”. or to demonstrate “allegiance to a particular section of the scientific community”.<sup>11</sup> Alternatively it may reflect careless citation practice or entrenched community beliefs and we will examine the latter in our case study.

### **Over- simplification**

Risk communication is complex and difficult but perhaps no more so than in public health where the risk may be anticipated or distant rather than existing and immediate. There is, therefore, a temptation to simplify messages with the objective of improving understanding. There is a great deal of merit in providing clear and simple instructions. However, as our case study demonstrates, over-simplification may impede transmission of the type and amount of information needed to make sense of a complex situation. This may have the perverse effect of preventing or discouraging

people from engaging in active management of their own health. In particular, a focus on text constructs, such as word and sentence length, may result in a loss of content richness such that the message is more easily read but less comprehensible. Zarcadoolas describes this as “communication by subtraction”.<sup>12</sup> Oversimplification of public health messages may be seen by an increasingly health literate public and a highly health literate health workforce as patronising. Leask argues that a convinced and convincing GP may be the cornerstone of a successful vaccination campaign.<sup>13</sup> Yet a policy position stated with certainty, which is then shaken by adverse events, may cause loss of confidence in the expert authority, greater than would have occurred had the uncertainty in the evidence been acknowledged and communicated. This factor may have contributed to the 2010/11 public response to the withdrawal of FluVax vaccination for children in Australia.<sup>14</sup>

We believe that it would be simplistic to suggest that public health policy and practice is based on evidence alone or that other factors are not involved in decision-making.<sup>15</sup> However, presenting guidelines as ‘evidence based’ opens them to critique particularly when proposals for public health policies involving compulsory measures are drawn from this evidence base.

### **Approach**

In order to explore and demonstrate the issues described above we use a case study. In our work we have encountered several cases where it is apparent that one or more of the factors described in Table 1 can be identified in guideline development. However, the case study we have chosen is relatively unique in incorporating all of these factors. Our case study is based on a review of national guidelines for seasonal influenza vaccination for HCWs in five countries: Australia, NZ, USA, Canada and the UK. (Table 2) We examined the recommendations of these documents and the evidence which was described as underpinning them. The objective here was not to provide an analysis of these documents but rather to draw from them examples of the factors described in Table 1 to explicate our argument. In particular, we focussed on the evidence base presented and whether these reflect the primary source. Our work is informed by a systematic review of evidence for the efficacy, effectiveness and safety of influenza vaccines carried out for a previous study.<sup>16</sup> This review was updated with searches within the Scopus database for the years January 2000-November 2011 using the keyword combination of: ((health care worker\* OR healthcare worker\* OR health care personnel OR healthcare personnel), AND influenza AND vaccin\* AND NOT pandemic).

### **Examination of the guidelines for health care worker vaccination**

There are clear guidelines, both in Australia and the other four countries reviewed, for HCWs to vaccinate against influenza. (Table 2) Vaccination for influenza is considered to be an efficacious public health intervention which reduces the burden of influenza illness and it can also be framed as an issue of occupational health and safety and respect for patient safety. Vaccination programs have been one of the greatest success stories of public health. One consequence of this is that there are strongly held beliefs amongst individuals working in infectious disease and many working in public health, that vaccination is beneficial and advantageous under any circumstances. There are recorded instances of transmission of influenza from HCWs to patients.<sup>17, 18</sup> and it is reasonable to believe that transmission rates are higher than

documented. However, there is also considerable resistance to influenza vaccine uptake: without significant efforts to encourage vaccination, staff vaccination rates are low.<sup>19, 20</sup> Even with significant encouragement and support, in the absence of mandatory requirements, staff uptake is usually well below the universal coverage required to best protect patients.<sup>19, 20</sup> In this paper we examine the gaps between evidence, guidelines and practice for HCW influenza vaccination rates.

We begin with the evidence. Seasonal influenza vaccines are around 80% effective in healthy adults, with the effectiveness being even higher when there is a close match between the vaccine and the circulating viral strain.<sup>21</sup> There is also some evidence that the HCW vaccination for influenza decreases staff illness and absenteeism<sup>22-24</sup> and is cost-effective with respect to both direct costs of health care acquired infection and indirect costs of staff absenteeism.<sup>25-28</sup>

Direct evidence that HCW vaccination reduces *transmission* of influenza virus in health care settings and reduces patient mortality is more difficult to find. Individual studies and a Cochrane review of influenza vaccination for aged-care workers (which draws on two RCTs and one cohort study) suggest there is some evidence that this intervention is effective in protecting the elderly in care settings.<sup>29</sup> A later Cochrane review, which pooled data from three cluster RCTs<sup>30-32</sup>, found no effect on influenza, pneumonia and death from pneumonia, although there was lower resident all-cause mortality and reduced influenza-like illness.<sup>33</sup> The Cochrane review<sup>33</sup> highlights this inconsistency and the authors suggest that it is the result of biased selection of subjects, and/or performance bias in that the studies were underpowered to detect the outcomes of interest because of low levels of vaccine uptake in the intervention arms of the studies. Either way, currently, there is a *paucity* of evidence to support substantial investment in HCW vaccination programs in order to protect patients from nosocomial influenza infection in hospital settings.

Beyond this, we suggest that it is problematic to *extend* evidence found in aged care setting to hospitals where visitors are more common and staff numbers larger and turning over more frequently. A single longitudinal observational hospital study found significant declines in nosocomial influenza infection amongst patients and staff when HCW influenza vaccination increased from 4% to 67%<sup>34</sup> but the level of evidence is low. None of the studies described above provide high quality evidence that vaccinating HCWs would result in statistically significant reductions in nosocomial seasonal influenza infection in hospital or clinic settings. Given the economic investment in influenza vaccination programs for HCWs, the absence of high quality evidence is striking.

However it can also be argued that such evidence is very difficult to collect.<sup>35</sup> RCTs would be impossible to conduct since these would require random selection of hospitals to mandatory HCW influenza vaccination or non-vaccination arms. Such an approach would be unethical for a number of reasons including infringement of personal autonomy and possible harms to HCWs from vaccination or non-vaccination. Such RCTs would also be extremely difficult to execute and prohibitively expensive. However, a natural experiment is currently underway with mandatory vaccination for influenza recently instituted at some US health institutions<sup>36</sup> and it could be feasible to compare these institutions with matched control institutions.

Despite the lack of evidence, guidelines in the countries examined are often underpinned by claims that such evidence exists. For example, the Australian Immunisation Handbook 9<sup>th</sup> Edition, in recommending the vaccination of HCWs, states “it has been shown that vaccinating [HCWs] protects those at high-risk”<sup>37, p.192</sup> and cites a single paper which relates to the use of vaccination of aged-care workers to protect the elderly in their care.<sup>32</sup> This paper and similar papers<sup>30, 31, 38</sup>, describing work in aged care settings, are cited repeatedly in support of guidelines for *universal* HCW vaccination, an example of citation bias (see Table 1). Selective reporting of findings may also introduce bias. For example, the 2010 Recommendations of the Advisory Committee on Immunization Practices (ACIP) which form the basis of the USA’s CDC recommendations states that “A review concluded that vaccination of HCP in settings in which patients also were vaccinated provided significant reductions in deaths among elderly patients from all causes and deaths from pneumonia.”<sup>39, p.26</sup> What ACIP recommendations *do not* state is the other finding of the cited review: “If patients were not vaccinated, staff immunisation had no effect”<sup>40, p.273</sup>. The authors of the ACIP recommendations have selectively used the finding from the review which supports their recommendations for HCW vaccination while failing to include the finding from the same review which does not support their case. In a similar example, the Canadian Statement on Seasonal Trivalent Inactivated Influenza Vaccine (TIV) for 2010-2011,<sup>41</sup> reports both the findings of the papers described above and the 2010 Cochrane review<sup>33</sup>, while glossing over the review’s findings as to the need for patient vaccination and potential bias in the included studies. It is highly probable that, in health care settings, most patients are neither vaccinated nor located in cloistered environs characteristic of aged care facilities. Therefore, it could be argued that there is, at present, no direct evidence to support universal HCW influenza vaccination.

Citation amplification is apparent in the numerous peer reviewed publications which advocate mandates for universal HCW influenza vaccination and in the immunisation recommendations listed in Table 2. For example, a Scopus database search for papers advocating compulsory universal HCW influenza vaccination published during 2010, which included reference to supportive evidence, identified 16 papers, all of which relied on one or more of four papers describing work in aged or long-term care settings<sup>30-32, 38</sup> or a single longitudinal observational study.<sup>34</sup> The literature advocating *universal* HCW influenza vaccination resembles an inverted pyramid – a large volume of review and commentary articles supported by a very small number of empirical studies carried out in long-term care settings. In addition, the guidelines listed in Table 1 are often used to lend legitimacy to the arguments for universal and compulsory influenza HCW vaccination.

Dead-end citation is evident in a discussion paper from the Australian influenza specialist group, an influential group with respect to Australian vaccination policy, which recommends that HCWs vaccinate against influenza thereby “indirectly protecting those most vulnerable to the virus”.<sup>42</sup> To support this recommendation the authors cite studies examining: HCW attitudes to vaccination<sup>43</sup>, ethical issues associated with HCW vaccination<sup>44, 45</sup> and risk of acquisition of influenza in non-vaccinated HCWs.<sup>46, 47</sup> None of these studies could be considered to provide direct evidence for the value of HCW influenza vaccination in the protection of patients. However, if the value of vaccination as a public health tool is considered beyond



question, reflecting a culturally shared belief, then the cited papers could be seen to provide background arguments for why HCWs should be targeted as a special case and for special measures.

Finally, health messages may be oversimplified. In a culture where vaccination is seen as universally 'good' and non-compliance as irrational nuanced messages about risks posed by disease and discussions about uncertainty in evidence, may be seen as unnecessary and potentially confusing. Oversimplification may also result in downplaying of the potential for adverse post-vaccination events. The Australian Influenza Specialist group position document<sup>42</sup> plays down adverse events describing them as "negative attitudes and misconceptions". In doing so, it does not acknowledge the burden of the occasional risks with seasonal influenza vaccines described later in the document of up to 10% of vaccinated individuals experiencing "symptoms mimicking a light influenza infection, such as fever" for up to 48 hours post vaccination.<sup>42</sup> A figure of 10% is high but may be seen with certain influenza vaccines although systemic reactions with placebo injections may also be as high.<sup>46</sup> Recent RCTs in healthy adults over the 2005-06 and 2006-07 showed that fever occurred post-vaccination in 3% of participants given active vaccines and 1% of participants in the placebo control arm, that is, there is evidence of a mild but real reaction in approximately 2% of vaccinated participants in what were mild influenza seasons.<sup>48</sup> A Canadian qualitative research study<sup>49</sup>, showed that unvaccinated HCWs valued the protective effects of vaccination but did not believe vaccines were effective. They also believed that the vaccine made them sick and/or that the focus of vaccination was to protect patients to the potential detriment of the HCWs.<sup>49</sup>

## **Implications for evidence-practice gaps**

### **(i) In the case study**

In summary, we contend that there are two principal factors characterising the evidence-guidelines-practice gap in HCW influenza vaccination: (i) obfuscation of uncertainty, in the evidence base and intervention efficacy (ii) oversimplification of the vaccination message. These factors reduce transparency and may increase mistrust between HCWs, institutional administrators and policy implementers. This has ramifications for other areas where staff goodwill and compliance are required. This may be particularly so if adverse events occur with other vaccines, such as the paediatric FluVax vaccine withdrawn from the Australian market in 2010.

In some sectors, the risk to patients of this guidelines-practice gap may be low and the principal adverse outcome may be increased staff absenteeism. However, in sectors such as aged care, intensive care and oncology, gaps in vaccine coverage of HCWs may place patients at considerable risk and compulsory vaccination of HCWs can be readily justified.<sup>50</sup> The provision of more complex and nuanced health information for HCWs may be beneficial, not only in terms of greater transparency but also in building trust between HCWs and administrators and policy makers. Balanced discussion of the uncertainty in the evidence and better recognition of the need for reciprocal responsibility of institutions towards HCWs, who place themselves at risk of adverse vaccination events, may increase both the level of trust and vaccine uptake. However, given the poor evidence base and the uncertainty about the degree of risk to patients from unvaccinated HCWs in many settings, it may be difficult to justify the degree of emphasis currently placed on mandating *universal* HCW vaccination. There

may be well-founded ethical reasons why we might expect HCWs to vaccinate.<sup>44, 50</sup> However, we suggest that, as a society, we should take particular care in making demands for strong actions and impositions on individual autonomy where the evidence base is poor.

Even with transparently drafted guidelines many HCWs may choose not to vaccinate. This may be difficult for many working in infectious disease control to accept. There are three courses of action which might be taken. First, greater efforts should be undertaken to collect more definitive evidence that universal HCW vaccination would make a difference to patient well-being. Modelling may provide some additional information.<sup>51</sup> Second, should it be decided that universal HCW vaccination can be justified on grounds other than evidence, then, in consultation with HCWs, systems should be adopted which acknowledge and compensate HCWs for harms experienced. Finally, it may be more useful to reinforce HCW vaccination programs where the evidence is stronger and target individuals working in high risk, relatively cloistered clinical areas. Compulsory vaccination programs in these areas could be allied with a strong emphasis on enhanced hygiene practice and staff support.

## **(ii) For guidelines generally**

There is a growing body of literature documenting and critiquing the influence of shared scientific or practitioner community belief, in concert with professional power and corporate interests, in shaping health policy and clinical practice. In 2009, questions were raised about conflicts of interest amongst scientists advising the WHO on pandemic planning<sup>52, 53</sup> in particular, why these advisors had “declarable financial and research ties with pharmaceutical companies producing antivirals and influenza vaccines”.<sup>53, p1274</sup> Additionally, there was criticism of the lack of communication about uncertainty both in the time projections and the evidence for benefits and harms associated with pandemic vaccines.<sup>53</sup> Similarly, papers<sup>54, 55</sup> examining the efficacy of antiviral drugs detailed concerns about drug company influence and called for independent data review. These cases, and similar concerns raised about the nature of evidence presentation in the climate change debate,<sup>52</sup> provide key lessons for guideline producers. Firstly, transparency of process is essential: the public and, in this case, HCWs, must be convinced that the guidelines are unbiased and evidence-based. Secondly, it is essential to acknowledge uncertainty and document the strength of evidence underpinning the guidelines. Evidence from deliberative democratic processes and risk communication theory and practice suggests that acknowledging uncertainty, in a context of respect for persons, can reduce the divisions between experts and lay publics, improve dialogue and increase policy legitimacy.<sup>54</sup> Disseminating half-truths and exaggerated claims are likely to increase mistrust, which spills into other areas of vaccine health promotion but, as Sandman and Lanard indicate, we do not have much evidence to support that claim.<sup>56</sup> Nevertheless, in Australia, there are clear guidelines on how to develop guidelines.<sup>57</sup> These require that the transition from evidence to guidelines be transparent and documented. It is no longer sufficient to simply provide a recommendation: the strength of the recommendation must be indicated and there are processes for documenting this.<sup>58-60</sup> Adhering to these processes would prevent many of the issues discussed in this paper.

## Conclusion

We have shown that evidence-practice gaps may arise, in part, because of problems with the nature and application of the evidence used to justify the guidelines. Many of the issues discussed in this case study are apparent in association with other clinical and public health guidelines. Although erasing the uncertainty in the evidence base, during the translation of evidence into clinical guidelines, may reinforce the presumed authority and accuracy of health guidelines, it may also lay the guidelines open to disrepute. Building guidelines on evidence which is inadequate, drawn from specific contexts which cannot be generalised to the larger group, and which rely on biased and poor citation practice, risks more than just guideline non-compliance or the perception that specific guidelines may be unwarranted. It risks the credibility of guidelines in general. Bringing guidelines into disrepute through the mechanisms described in this paper puts at risk the many benefits that they afford. Our plea is for greater transparency and honesty in the communication of the uncertainty in the evidence underpinning guidelines.

**Table 1: Influential factors contributing to evidence-guidelines gaps**

1. **Paucity of evidence:** a lack of evidence to support a claim often because the evidence is difficult to collect.
2. **Evidence extension:** over-extension or amplification of existing evidence collected for specific cases but applied on a broader level where its applicability is questionable.
3. **Citation bias:** amplification of evidence by selective citation in which relevant (but conflicting) research is ignored in an attempt to support particular views.
4. **Citation amplification:** evidence bias by selective citation practice where studies, regardless of whether these are influential or peripheral papers, are cited repeatedly in support of a particular view.
5. **Dead-end citation:** citation(s) to research papers which do not contain evidence in support of a claim
6. **Oversimplification:** over-simplification of evidence during translation into health education messages.

**Table 2: List of immunisation guidelines and supportive documents**

<b>Country</b>	<b>Auspiced by</b>	<b>Document</b>	<b>Nature of document</b>
Australia	Department of Health and Ageing; NHMRC	Australian Immunisation Handbook 9 <sup>th</sup> Edition 2008, Section 3.9 Influenza.	Advisory with evidence
	Influenza Specialist Group	Influenza Vaccination among Health Care Workers 2009	Discussion paper
U.K.	Department of Health	Green Book	Advisory
	Joint committee on Vaccination and Immunisation	Advice on H1N1 and 2010/11 seasonal influenza vaccination programmes, 23 July 2010  JCVI statement on seasonal influenza vaccination, 30 December 2010	Advisory
	Department of Health	Protect your patients, your family, yourself: more information for health professionals about seasonal influenza vaccination, 2010	Leaflet directed at HCWs, includes evidence
U.S.A.	Center for Disease Control and Prevention	Morbidity and Mortality Weekly Report ( <i>MMWR</i> ). Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010, August 6, 2010 / Vol. 59 / No. RR-8	Advisory with evidence
New Zealand	Ministry of Health	Immunisation Handbook May 2011 Section 15 Influenza	Advisory
	National Influenza Strategy group	Influenza Medical Website	Advise and logistical support
Canada	Public Health Agency of Canada	Canada Communicable Disease Report. Vol. 36, 6 <sup>th</sup> August 2010. Statement on Seasonal Trivalent Inactivated Influenza Vaccine (TIV) for 2010-2011	Advisory with evidence

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